

(c) detecting the presence of the amplified sequence;

wherein detection of the amplified sequence indicates that the sample contains PoEV.

### **REMARKS**

Claims 43-65 are pending in the application. Claims 44, 45, 47, and 50 have been canceled without prejudice. Claims 43, 48, 49, 56, 57, and 62 have been amended. Support for the amendments may be found throughout the specification, including the claims as originally filed. No new matter has been added.

Cancellation and/or amendment of claims should in no way be construed as an acquiescence, narrowing, or surrender of any subject matter. The amendments are being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the application. Applicants reserve the option to prosecute further the originally filed claims, or similar ones, in the instant or a subsequent patent application.

In response to the comments at page 2 of the Office Action relating to the group and species election, Applicant's wish to reiterate that the election of group I (claims 43-64) and SEQ ID NO: 13 as the species in the response to Restriction Requirement dated December 12, 2001 were made **with traverse**. Furthermore, Applicant's distinctly and specifically pointed out the errors in the restriction requirement in conjunction with making the election **with traverse**.

### **Claims 43-47 and 49-56 Rejected under 35 U.S.C. §112, first paragraph**

Claims 43-47 and 49-56 were rejected under 35 U.S.C. §112, first paragraph, for reasons of written description. The Action states that:

\*\*\*In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, SEQ ID NO 1, 2, 3 and 9 are the only species whose complete structure is disclosed. The specification does not provide any disclosure as to what would have been the sequence structure of any other sequence encompassed [in] the claimed genus of polypeptides. (Office Action at 3).

The rejection is respectfully traversed.

The claimed invention is directed to polynucleotide fragments comprising nucleotides 5620 to 7590 of SEQ ID NO: 3, sequences having at least 75% identity thereto, and fragments of sequences having at least 90% identity to nucleotides 5620 to 7590 of SEQ ID NO: 3. The specification clearly conveys to one skilled in the art that the Applicants were in possession of the claimed genera at the time the application was filed. The specification provides the complete coding region for the ENV polypeptide, comprising nucleotides 5620 to 7590 of SEQ ID NO: 3 (see e.g., Figure 3). Figure 4 and Example 9 (at pages 30-34 of the specification) additionally provide the complete sequence of a modified version of the ENV gene isolated from RAJI cells infected with PoEV (SEQ ID NO: 9). The specification further teaches (see e.g., pages 15-16 of the specification) that conservative amino acid replacements may be made while retaining the function of a protein. The Specification also discloses that nucleotide sequences having at least 75% identity to SEQ ID NO: 3 may be isolated by their ability to hybridize with this sequence (see e.g., pages 7-8). Therefore, as required by the interim written description guidelines, the specification provides a representative number of species from the claimed genera. Accordingly, the specification clearly supports that Applicants' were in possession of the claimed invention at the time of filing the Application. In view thereof, reconsideration and withdrawal of the rejection are respectfully requested.

**Claims 43-47 and 49-56 Rejected under 35 U.S.C. §112, first paragraph**

Claims 1-5 were rejected under 35 U.S.C. §112, first paragraph, for reasons of enablement. In particular, the action states that:

\*\*\*[T]he specification, while being enabling for (i) an isolated polynucleotide disclosed in SEQ ID NO: 1, 2 and 3 wherein the polynucleotides of SEQ ID NO: 2 and 3 wherein the polynucleotides of SEQ ID NO 2 and 3 have three open reading frames (ORFs) of 524 (SEQ ID NO 4), 1194 (SEQ ID NO 5), and 656 amino acids each (SEQ ID NO 6) (ii) an isolated polynucleotide disclosed in SEQ ID NO 9 which encodes the protein disclosed in SEQ ID NO 10, vector comprising the polynucleotides of (i) and (ii), does not reasonably provide enablement for any other claimed embodiments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. (Office Action at 3-4).

The Rejection is respectfully traversed.

Applicant's wish to note that claims 1-5 are no longer pending in the application. However, in an effort to expedite prosecution of this application, Applicant's will address this rejection as it is appropriate and applicable to one or more of the currently pending claims 43-65.

The claimed invention is directed to polynucleotide fragments comprising nucleotides 5620 to 7590 of SEQ ID NO: 3, sequences having at least 75% identity thereto, and fragments of sequences having at least 90% identity to nucleotides 5620 to 7590 of SEQ ID NO: 3. As discussed above, the specification provides the complete coding region for the ENV polypeptide (comprising nucleotides 5620 to 7590 of SEQ ID NO: 3) and a modified version of the ENV gene isolated from RAJI cells infected with PoEV (SEQ ID NO: 9). The specification also provides a number of working examples supporting the claimed invention. For example, Examples 1 to 4 (at pages 19-23) describe the cloning and sequencing of viral DNA sequences, including the sequence encoding the ENV polypeptide from PoEV. Example 9 (at pages 30-34) describes the amplification and analysis of PoEV sequences from PoEV infected RAJI cells, including analysis of the env gene from PoEV. The Specification also teaches that nucleotide sequences having at least 75% identity to SEQ ID NO: 3 may be isolated by their ability to hybridize with these sequences (see e.g., pages 7-8). Furthermore, use of oligonucleotides for detection of PoEV is described in the specification (see e.g., pages 7-8). Additionally, use of pairs of oligonucleotide primers for PCR amplification of PoEV is described in the specification, for example, at pages 10-11 and in the Examples. The Examples section also provides the sequences for specific PoEV primers which were used for amplification of PoEV sequences (see e.g., pages 28-33). Accordingly, the specification clearly provides sufficient guidance, working examples, and evidence as to how an artisan would have made and used the claimed invention without undue experimentation. In view thereof, reconsideration and withdrawal of the rejection are respectfully requested.

**Claims 57, 58, and 60 Rejected under 35 U.S.C. §112, second paragraph**

Claims 57, 58, and 60 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. In particular, the Action states that claim 57 is indefinite because it is dependent on claim 56 which recites oligonucleotides of at least 30 nucleotides, however, the oligonucleotides recited in SEQ ID NO: 13 is only 20 nucleotides. Claim 57 has been amended so that it is no longer dependent upon claim 56. In view thereof, reconsideration and withdrawal of the rejection is respectfully requested.

**Claims 43-47 and 49-64 Rejected under 35 U.S.C. §102(e)**

Claims 43-47 and 49-64 were rejected under 35 U.S.C. §102(e) as being anticipated by Fishman et al. US Patent No. 6,190,861. The action states that:

Fishman teaches swine retroviruses and methods of using such. The sequence of SEQ ID NO 1 of the instant application has more than 86% sequence identity over the sequence of SEQ ID NO 3 of Fishman et al whereas SEQ ID NO 3 of the instant application has more than 76% sequence identity over the sequence of SEQ ID NO 3 of Fishman et al. The sequence of SEQ ID NO 9 of the instant application has more than 97% sequence identity over the sequence of SEQ ID NO 3 of Fishman. The sequence of SEQ ID NO 13 and 14 of the instant application also have 100% identity to parts of SEQ ID NO 3 of Fishman. Fishman et al also teaches method of detection and other methods (see columns 1-38 of Fishman. Accordingly, the invention of claims 43-47 and 49-64 is anticipated by Fishman. (Office Action at 7).

The rejection is respectfully traversed.

The claimed invention is directed to polynucleotide fragments comprising nucleotides 5620 to 7590 of SEQ ID NO: 3, sequences having at least 75% identity thereto, and fragments of sequences having at least 90% identity to nucleotides 5620 to 7590 of SEQ ID NO: 3. Applicants have conducted sequence comparisons of the env gene of Applicant's SEQ ID NO: 3 (nucleotides 5620 to 7590) with the corresponding sequences of SEQ ID NOs: 1, 2, and 3 of Fishman. The overall sequence homology is 60%, 62%, and 59% for sequences 1, 2, and 3 of Fishman, respectively. Even over shorter regions, the sequence homologies are less than 87%, as illustrated in the following table. Note that the comparisons were performed using the Blast 2

program, in which homologies must be above a certain threshold to be scored; hence some of the comparisons are indicated as only "<75%."

	Fishman SEQ ID NO: 1	Fishman SEQ ID NO: 2	Fishman SEQ ID NO: 3
Homology to the specified sections of Applicant's SEQ ID NO: 3	5620-5876 = 81%	5620-5680 = <75%	5620-5876 = 80%
	5877-6017 = <75%	5681-5896 = 79%	5877-6017 = <75%
	6018-6098 = 77%	5897-6017 = <75%	6018-6098 = 77%
	6099-6147 = <75%	6018-6095 = 75%	6099-6147 = <75%
	6148-6258 = 83%	6159-6246 = 86%	6148-6257 = 80%
	6259-6515 = <75%	6245-6499 = <75%	6258-6515 = <75%
	6516-7561 = 79%	6500-7590 = 85%	6516-7561 = 78%
	7566-7590 = <75%		7562-7590 = <75%
Overall Homology	60%	62%	59%

Furthermore, Applicant's note that Fishman does not teach *oligonucleotides* having the nucleotide sequence set forth in SEQ ID NO: 13 or 14.

Accordingly, the claimed invention is not anticipated by Fishman. In view thereof, reconsideration and withdrawal of the rejections are respectfully requested.

**CONCLUSION**

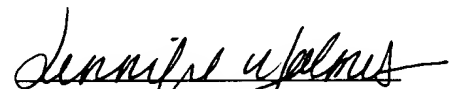
For the reasons presented, Applicants respectfully request that the pending rejections be reconsidered and withdrawn. Applicants believe that the claims are now in condition for allowance and early notification to this effect is earnestly solicited.

If there are any fees in connection with the filing of this Response, please charge the fees to our **Deposit Account No. 06-1448**. If a fee is required for an extension of time under 37 C.F.R. §1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,  
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**Marked-up version of the amendments to the claims:**

Please amend claims 43, 48, 49, 56, 57, and 62 as set forth below:

43. (Amended)        An isolated polynucleotide fragment comprising:
- (a)    a nucleotide sequence [set forth in SEQ ID NO: 1, 2, 3 or 9] having nucleotides 5620 to 7590 of SEQ ID NO: 3;
  - (b)    [a portion of a nucleotide sequence set forth in (a) which encodes for at least one porcine retrovirus polypeptide;
  - (c)]    a nucleotide sequence which has at least 75% identity to [a] the sequence set forth in (a) [or (b)]; or
  - [(d)](c)        a nucleotide sequence which is complementary to a nucleotide sequence set forth in [(a), (b) or (c)] (a) or (b).
48. (Amended)        An isolated polynucleotide fragment encoding for a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: [4, 5,] 6 or 10.
49. (Amended)        An isolated polynucleotide fragment comprising a nucleotide sequence which has at least 90% identity to a sequence having nucleotides 5620 to 7590 of SEQ ID NO: 3 [set forth in SEQ ID NO: 1, 2, 3 or 9], or a nucleotide sequence which is complementary thereto.
56. (Amended)        An oligonucleotide comprising at least 30 nucleotides which are fully complementary to a sequence set forth in claim [43] 49.
57. (Amended)        An oligonucleotide [according to claim 56 which has] having the nucleotide sequence set forth in SEQ ID NO: 7, 8, 11, 12, 13 or 14.

62. (Amended) A pair of oligonucleotide primers for use in PCR amplification wherein each primer comprises at least 10 nucleotides complementary to a sequence to a sequence having nucleotides 5620 to 7590 of SEQ ID NO: 3 [set forth in SEQ ID NO: 1, 2, 3 or 9], or a sequence complementary to a sequence having nucleotides 5620 to 7590 of SEQ ID NO: 3 [set forth in SEQ ID NO: 1, 2, 3 or 9].